# A Successful Protocol for the Use of Pulse Oximetry to Classify Arterial Oxygenation into Four Fuzzy Categories

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## ABSTRACT

*Pulse oximetry is widely used in critical care medicine to noninvasively estimate arterial hemoglobin oxygen saturation. Despite the obvious benefits of using pulse oximetry to detect life threatening desaturations, it is unknown how well pulse oximetry is able to predict the finer graduations of arterial oxygenation needed for clinical decision making.*

*A computerized protocol was developed for the use of pulse oximetry to classify arterial oxygenation into four fuzzy categories and tested in a prospective clinical trial which compared the oxygenation category assigned by the protocol to one assigned by a respiratory therapist. In 3,742 classifications from 15 patients over a seven month period, the protocol showed 96% agreement with the therapists in the direction of therapy and 75% agreement with the oxygenation classes assigned by the therapists.*

## INTRODUCTION

Pulse oximetry is widely used in critical care medicine to noninvasively measure arterial hemoglobin saturation ($SaO_2$). Although clinical practice guidelines exist for the use of pulse oximetry, they leave several important questions relating to the clinical use of pulse oximetry unanswered. [1]

1. How accurately does the pulse oximeter saturation ($SpO_2$) measure $SaO_2$ ?
2. How do these values relate to the arterial partial pressure of oxygen ($PaO_2$) ?
   a. How do you use $SpO_2$ to determine arterial oxygenation?
   b. How should $SpO_2$ information be used in clinical decision making?
3. How do the "weasel words" used in the guidelines translate into specific values for the various clinical measurements and the intervals between reevaluation of the $SpO_2$–$SaO_2$ relationship? [2]

This paper discusses the development of an intensive care unit (ICU) computerized protocol that successfully addresses the aforementioned questions and classifies arterial oxygenation into four fuzzy categories (Table 2) by estimating the patient's $PaO_2$ from the current $SpO_2$, past arterial blood gas (ABG) data—$PaO_2$, $SaO_2$, $SpO_2$, and the presence or absence of barotrauma.

The $SpO_2$ protocol was designed to assess oxygenation as part of a set of protocols for managing mechanical ventilation. [3,4,5]

## METHODS

### Knowledge Engineering

The protocol logic was developed using a consensus committee to compile a list of common assumptions in the clinical use of $SpO_2$ monitoring:

1. $SpO_2$ and $PaO_2$ are correlated.
2. $SpO_2$ and $SaO_2$ are not the same, but the gradient between them is small (< 4 %) and stable within any given patient; therefore, single point calibration between $PaO_2$ and $SpO_2$ is adequate.
3. A patient's oxyhemoglobin dissociation curve may be shifted; however, the shift is stable.

Several different $SpO_2$ protocols based on these common assumptions were developed and tested. Retrospective reviews and tests of these initial protocols revealed several fallacies in these assumptions:

1. $SpO_2$ and $PaO_2$ are not necessarily correlated. In 25% of cases, $PaO_2$ and $SpO_2$ do not even move in the same direction. $SpO_2$ changes also reflect changes in parameters other than $PaO_2$. Carboxyhemoglobin (COHb), methemoglobin (MetHb), and peripheral blood flow also dramatically affect $SpO_2$.
2. $SpO_2$ and $SaO_2$ often differ widely (by > 6 %) and their difference often change dramatically from the time of one blood gas to the next.
3. Shifts of the patient's apparent oxyhemoglobin dissociation curve ($SpO_2$ vs. $PaO_2$) may be quite large (>20 mmHg) and also vary dramatically from one blood gas to the next.

These problems indicate single point calibrations between $PaO_2$ and $SpO_2$ are not adequate, and indeed $PaO_2$ and $SpO_2$ may need to be recalibrated several times daily.

### $SpO_2$ Protocol

The current protocol (Figure 1) uses a combination of quality assurance rules, mathematical models,

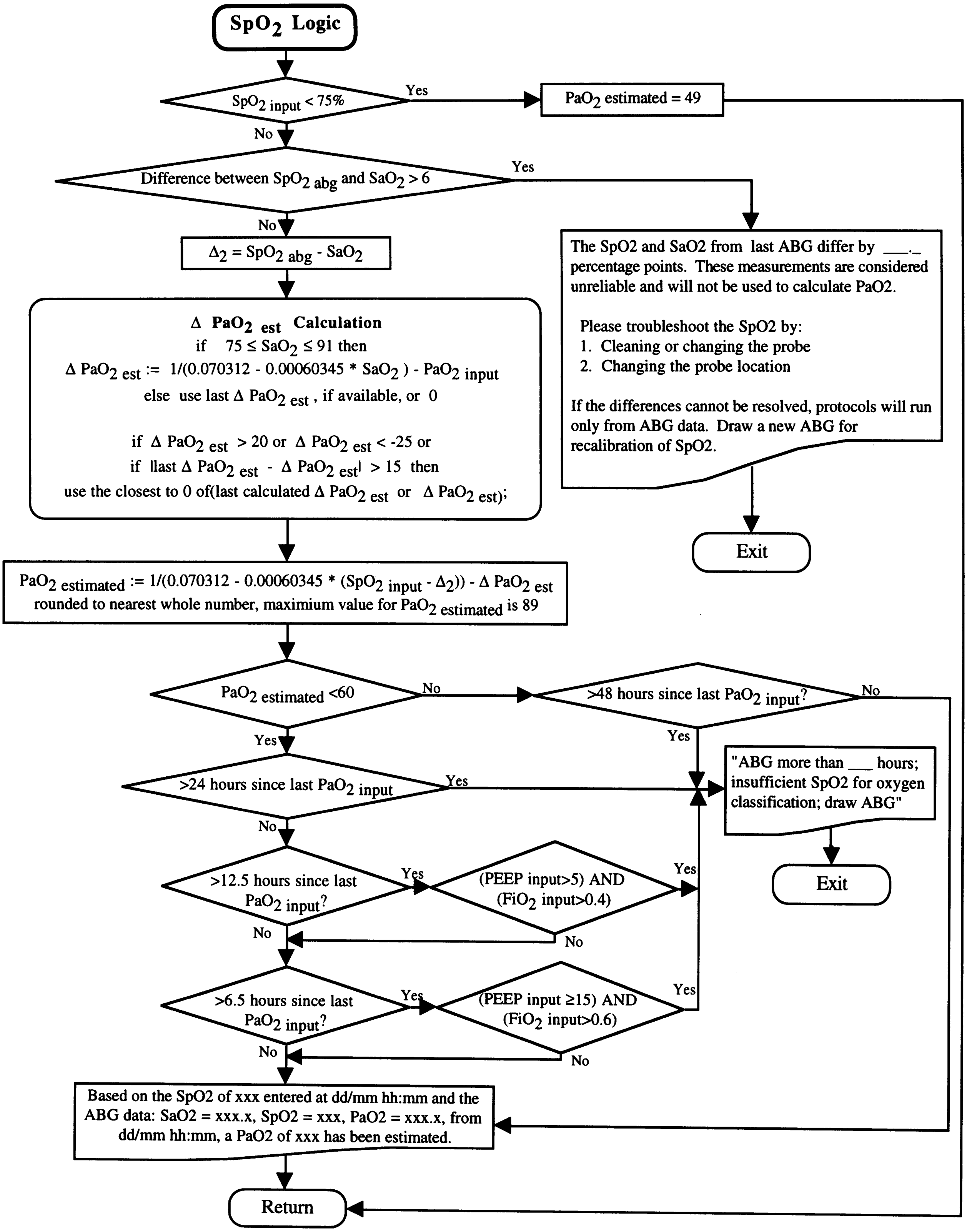


Figure 1. SpO2 Protocol in Flow Diagram Form

and thresholds to classify arterial oxygenation into one of the four oxygenation classes.

1. The entered $SpO_2$ is checked for a life threateningly low saturation ($SpO_2 < 75\%$), so the ventilator management protocols can quickly respond without the need for an ABG or other data.
2. A quality assurance check is made to compare the difference between the $SpO_2$ measured at the time of the blood gas ($SpO_{2\,abg}$) and $SaO_2$. If the difference is greater than 6 percentage points, the protocol exits and asks the clinician to try to reduce or eliminate the difference by changing, cleaning, or moving the $SpO_2$ probe.
3. Oxyhemoglobin curve shift parameters are calculated. $\Delta PaO_2est$ (Eq. 1) adjusts for changes in temperature and acid balance ($pCO_2$, $[HCO_3^-]$, pH), and $\Delta_2$ (Eq. 2) adjusts the curve for factors, such as COHb and MetHb, which the pulse oximeter misinterprets as oxyhemoglobin.

$$\Delta PaO_2 est = \frac{1}{0.070312-0.00060345 \cdot SpO_{2\,abg}} - PaO_2 \quad (1)$$

$$\Delta_2 = SpO_{2\,abg} - SaO_2 \quad (2)$$

Quality assurance checks are also made on $\Delta PaO_2est$ to assure that it is within a reasonable range (-25 to 20 mmHg) and it is no more than 15 mmHg from the last value. Violations of these constraints cause the calculated $\Delta PaO_2est$ to be replaced by the last stored value of $\Delta PaO_2est$ if its magnitude is less than that of the calculated value. While $\Delta PaO_2est$ and $\Delta_2$ are recalculated every time a protocol $SpO_2$ is entered, they only change when a new $PaO_2$, $SaO_2$, $SpO_2$ set are available from an ABG.

4. $PaO_2$ is estimated from a shifted ($\Delta PaO_2est$ and $\Delta_2$) hyperbolic curve (Eq. 3), fit to the standard oxyhemoglobin dissociation curve at 37° C, pHa = 7.40 between $SaO_2$ of 75% and 93%.

$$PaO_2 est = \frac{1}{0.070312-0.00060345 \cdot (SpO_2-\Delta_2)} - \Delta PaO_2 \quad (3)$$

Figure 2 illustrates the shifting effect of $\Delta PaO_2est$ and $\Delta_2$ on the oxyhemoglobin dissociation curve. [6] $\Delta PaO_2est$ and $\Delta_2$ model the changes in both position and shape of the dissociation curve resulting from $SpO_2$ measurement problems and oxygen-hemoglobin affinity changes due to variations in acid–base balance, temperature, 2,3-DPG, and molecules other than oxygen binding to the hemoglobin, such as in carbon monoxide poisoning. [7]

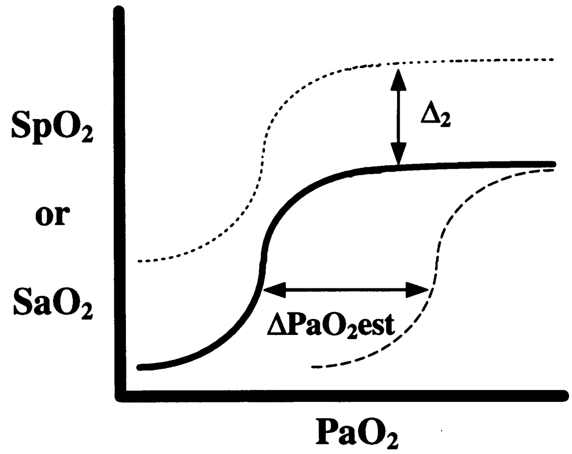


Figure 2. The effects of $\Delta PaO_2est$ and $\Delta_2$ on the oxyhemoglobin dissociation curve. [6,7]

Note: Scale and shape of curve have been exaggerated to emphasize the shift parameters.

5. Additional protocol logic was added to provide quality assurance for $SpO_2$ measurements. By limiting the interval between recalibrations, we were able to improve both the data quality and accuracy. We chose the level of patient support and $O_2$ Class as the guides for setting the recalibration interval. $O_2$ Class is assigned by a separate module using $PaO_2est$ and the membership functions listed in Table 2. Level of support is classified as either high, medium, or low and is based upon the Positive End Expiratory Pressure (PEEP) level and the inspired oxygen fraction ($FiO_2$). The three levels of support, with the defining PEEP and $FiO_2$ levels, and the recalibration intervals are defined in Table 1. The recalibration interval is reevaluated every time a protocol $SpO_2$ is entered.

Table 1. Support Levels and Recalibration Intervals

| $O_2$ Class (Table 2) | Support Level | Thresholds | Recalibration Interval |
|---|---|---|---|
| S | any | | 48.0 hours |
| T, M, A | low | $FiO_2 < 0.4$<br>$PEEP < 5$ | 24.0 hours |
| T, M, A | medium | $0.4 < FiO_2 < 0.6$<br>$5 < PEEP < 15$ | 12.5 hours |
| T, M, A | high | $0.6 < FiO_2$<br>$15 < PEEP$ | 6.5 hours |

S = Satisfactory, A = Acceptable, M = Marginal, T = Threatening

**Retrospective Evaluation of SpO2 Protocol**

Computerized records of 14,424 paired ABG and $SpO_2$ measurements from 233 ARDS patients were used to retrospectively test the protocol. The first ABG was used to calculated $\Delta PaO_2est$ and $\Delta_2$. The $SpO_2$ paired with the second ABG was used to calculate $PaO_2$est. $PaO_2$est was then assigned to one of four clinically important oxygenation classes ($O_2$ Classes) based on its value and the presence or absence of barotrauma. The measured $PaO_2$ ($PaO_2$meas) from the second ABG was also assigned to one of the four classes and the results of these classifications compared in a contingency table. [6]

Table 2. Fuzzy Arterial Oxygenation Classification Membership Functions

| $O_2$ Class | Barotrauma | Nonbarotrauma |
|---|---|---|
| Threatening | PaO2 < 50 | PaO2 < 50 |
| Marginal | 50 ≤ PaO2 < 55 | 50 ≤ PaO2 < 60 |
| Acceptable | 55 ≤ PaO2 < 60 | 60 ≤ PaO2 < 68 |
| Satisfactory | 60 ≤ PaO2 | 68 ≤ PaO2 |

**Prospective Clinical Trial of $SpO_2$ Protocol**

The $SpO_2$ protocol was tested in a prospective trial comparing the $O_2$ Class assigned by the protocols to those assigned by respiratory therapists (RTs). The RTs scoring the patients were the staff of the Shock Trauma Intermountain Respiratory ICU (STRICU) at LDS Hospital. The STRICU staff has been using the ARDS protocols and assigning oxygenation classes to patients on a regular basis for the last seven years. [3,4,5]

The ventilator management protocols use the $O_2$ Class from the $SpO_2$ protocol unless the RT-assigned $O_2$ Class would have resulted in a change in therapy in the opposite direction (protocol would increase therapy, but RT would have reduced therapy). In the event of these disagreements, an ABG was drawn to assign an $O_2$ Class and recalibrate the shift parameters.

The $SpO_2$ protocol was subjected to a three month evaluation period, during which we monitored the protocol performance and responded to all real and perceived problems with the protocol. The $SpO_2$ protocol has been in daily clinical use for an additional four months in the ICUs of LDS Hospital and McKay-Dee Hospital Center, in Ogden, Utah.

## RESULTS AND DISCUSSION

**Retrospective Analysis Results**

Table 3 compares oxygenation classifications from $PaO_2$meas and $PaO_2$est using the barotrauma oxygen classification functions.

The data was further lumped into two groups to assess the direction of subsequent therapy:

Increase therapy (↑ Tx) :

| $O_2$ Classes | |
|---|---|
| a. marginal | (see Table 2 for |
| b. threatening | for definitions ) |

Decrease or maintain therapy (↓/= Tx) :

| $O_2$ Classes | |
|---|---|
| a. acceptable | (see Table 2 for |
| b. satisfactory | for definitions ) |

Comparison of the appropriateness of the oxygenation classifications from $PaO_2$est and $PaO_2$meas shows that $PaO_2$est drives therapy in the proper direction 84% of the time (Table 4).

Table 3. Retrospective Analysis of $PaO_2$est using Barotrauma $O_2$ Class Thresholds

| | | $O_2$ Class from $PaO_2$est | | | | |
|---|---|---|---|---|---|---|
| $O_2$ | | T | M. | A | S | Σ |
| Class | T | 1,581 | 351 | 111 | 104 | 2,147 |
| from | M | 583 | 957 | 554 | 229 | 2,393 |
| $PaO_2$ | A | 178 | 606 | 985 | 871 | 2,640 |
| meas | S | 105 | 304 | 957 | 5,880 | 7,246 |
| | Σ | 2,447 | 2,218 | 2,607 | 7,154 | 14,426 |

S=Satisfactory, A=Acceptable, M=Marginal, T=Threatening

Table 4. Retrospective Analysis of Therapy Changes

| | | $PaO_2$est | |
|---|---|---|---|
| | | ↑ Tx | ↓/= Tx |
| $PaO_2$ | ↑ Tx | 24.07% | 7.4% |
| meas | ↓/= Tx | 8.27% | 60.26% |

↑ Tx : Increase Therapy ↓/= Tx : Decrease or Maintain Therapy

**Prospective Clinical Trial Results**

The data from the prospective study, shown in Table 4, agree well with the results of the retrospective study. In 15 patients at two different hospitals, the protocol and RT $O_2$ Classes show 76.7 % agreement and are within one category in 98.9 % of the instances. Comparison of the direction of therapy change indicated a 96.1% agreement (Table 5).

Table 4. Prospective Study of $SpO_2$ Protocol

| | | $O_2$ Class from $SpO_2$ | | | | |
|---|---|---|---|---|---|---|
| | | T | M. | A | S | Σ |
| $O_2$ | T | 5 | 8 | 2 | 0 | 15 |
| Class | M | 20 | 246 | 76 | 18 | 360 |
| from | A | 3 | 30 | 124 | 300 | 457 |
| RT | S | 0 | 17 | 394 | 2,499 | 2,910 |
| | Σ | 28 | 301 | 596 | 2,817 | 3,742 |

S=Satisfactory, A=Acceptable, M=Marginal, T=Threatening

Table 5. Prospective Study of Therapy Changes

| | | $SpO_2$ | |
|---|---|---|---|
| | | ↑ Tx | ↓/= Tx |
| RT | ↑ Tx | 7.46% | 2.57% |
| | ↓/= Tx | 1.34% | 88.64% |

↑ Tx : Increase Therapy ↓/= Tx : Decrease or Maintain Therapy

Of the 146 instances where the RT and the $SpO_2$ protocol disagreed on the direction therapy should be adjusted, 96 were potentially inappropriate therapy reductions. The resolution of these 96 events is summarized in Table 6.

Table 6. Resolution of $SpO_2$ Protocol – RT Disagreement

| Event | | N |
|---|---|---|
| ABG drawn | | 37 |
| Results agreed with Protocol | 18 | |
| Results agreed with RT | 19 | |
| No follow-up ABG | | 27 |
| Protocol rerun with different data | | 32 |
| | | 96 |

The largest single cause of these disagreements was data quality:

- bad or missing values for ABG-associated $SpO_2$
- poor agreement between $SpO_2$ and $SaO_2$
- use of last stored $\Delta PaO_2$est because calculated value does not meet quality assurance criteria (**$SpO_2$ Protocol**, item 3).

The next most common cause of disagreements was the calculated $PaO_2$est. $PaO_2$est was often incorrect in patients whose acid balance or temperature had changed by a clinically important amount since the last ABG. Misunderstandings of protocol function and incorrect "guesstimates" of the $PaO_2$ by clinical personnel also resulted in a large number of disagreements in assigning oxygen classifications.

Most of the disagreements on the direction of therapy were due to $PaO_2$est overlapping, by less than 2 mmHg, into an $O_2$ Class immediately adjacent to the clinician assigned $O_2$ Class For example, $PaO_2$est = 54 in a patient with the presence of barotrauma which yields an $O_2$ Class of Marginal while the clinician estimates the $O_2$ Class to be Acceptable. This results in both different classifications and disagreement on the direction in which therapy should change.

None of the 96 disagreements resulted in negative patient outcomes or life-threatening hypoxemia.

Of the 32 instances where the protocol was rerun, more than half were rerun because of data entry and data quality errors.

## CONCLUSIONS

This project has lead to several interesting conclusions many of which can be generalized to other medical measurements and to any protocols or practice guidelines which use them.

1. $SpO_2$ and $PaO_2$ are not as well correlated as most clinicians think.
2. Protocols must include a great deal of quality assurance logic to be reliable.
3. Human decision making with $SpO_2$ is widely varied and has little formal quality assurance.
4. It is very difficult to extract and effect rules and standards for $SpO_2$, a measurement that most clinicians feel is essential to the management of ICU patients.

Despite these problems, we have successfully created a protocol that standardizes the classification of arterial oxygenation assessed by pulse oximetry. This protocol may have application within pulse oximetry devices and ventilators in any clinical setting where $SpO_2$ is routinely monitored. Home care, assisting living centers, and emergency medical transport are only a few of the settings in which this protocol and others like it could be important assets.

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